K113526

FEB 16 2012

510(k) SUMMARY

Company Name: Medos International Sarl

Company Address: Chemin-Blanc 38
CH 2400 LeLocle, Switzerland

Phone: (508) 828-3421

Contact Person: Jocelyn Raposo, Senior Regulatory Affairs Specialist

Date: February 15, 2012

Name of the Device:

Propriety / Trade Name: Codman Certas Programmable Valve System
Codman Certas Therapy Management System

Product Code	Description
82-8800	Certas Inline Valve (includes a Priming Adapter)
82-8801	Certas Inline Valve with Accessories
82-8802	Certas Inline Valve with Accessories (unitized distal catheter)
82-8804	Certas Inline Valve with Siphonguard (includes a Priming Adapter)
82-8805	Certas Inline Valve with Siphonguard and Accessories
82-8806	Certas Inline Valve with Siphonguard and Accessories (unitized distal catheter)

Common Name: Hydrocephalus Shunt System

Classification: Class II (JXG)
Central Nervous System Fluid Shunt and Components

Legally Marketed Predicate Devices:

K112156 – Certas Programmable Valve System

Device Description:

The Certas Programmable Valve System is designed for shunting cerebrospinal fluid (CSF) for the treatment of hydrocephalus. The valve can be set to a choice of eight opening pressure settings for constant intraventricular pressure and drainage of CSF. The Therapy Management System allows the user to non-invasively adjust the opening pressure setting before and after implant.

The Certas Programmable Valve is available with and without the legally marketed SIPHONGUARD CSF Control Device and the Codman BACTISEAL Catheters as well as accessories needed to facilitate placement and use of the valve.

Intended Use:

The Certas Programmable Valve is an implantable device that provides constant intraventricular pressure and drainage of CSF for the management of hydrocephalus.

The Certas Therapy Management System allows the noninvasive reading or adjustment of the valve setting.

Technological Comparison:

The Certas Programmable Valve System with a 5 year shelf life is substantially equivalent to the predicate Certas Programmable Valve System with a 1 year shelf life. No changes are being made to the intended use, performance characteristics, materials, and principles of operation of the valve or its accessories. The 5-year shelf life applies to the Certas Programmable Valve Systems that are not packaged with a Bactiseal catheter. The shelf life of the Therapy Management System is not changing.

Performance Data:

Codman has performed both packaging and product stability testing to demonstrate that the packaging integrity and product functionality is maintained for 5 years. The packaging stability study shows that there was no change in post-sterile seal strength after accelerated aging. The product stability testing evaluated Adjustment and Indication capability, Pressure-Flow, as well as Leak and Reflux testing per EN ISO 7197:2009 after 5 years of accelerated aging. The test results demonstrate that the Certas Valve is substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Medos International SARL
c/o Codman & Shurtleff, Inc.
Ms. Jocelyn Raposo
Senior Regulatory Affairs Specialist
3325 Paramount Drive
Raynham, MA 02767

FEB 16 2012

Re: K113526
Trade/Device Name: CODMAN CERTAS Programmable Valve System
CODMAN CERTAS Therapy Management System
Regulation Number: 21 CFR 882.5550
Regulation Name: Central Nervous System Fluid Shunt and Components
Regulatory Class: Class II
Product Code: JXG
Dated: January 17, 2012
Received: January 18, 2012

Dear Ms. Raposo:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic, Neurological,
and Ear, Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K113526

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The CODMAN Certas Therapy Management System allows the noninvasive reading or adjustment of the valve setting.

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Ophthalmic, Neurological and Ear,
Nose and Throat Devices

510(k) Number K113526